UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/727,383 | 12/02/2003 | Paula M. Jardieu | P0790C4D1C2 | 7551 |

9157 7590 01/26/2005

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

| EXAMINER | |
|---|---|
| HADDAD, MAHER M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/727,383 | JARDIEU ET AL. | |
| | Examiner | Art Unit | |
| | Maher M. Haddad | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5,8,10,12-14,16 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8,10,12-14,16 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~10/25/04~~. 11.15.04 & 3.8.04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-5, 8, 10, 12-14, 16 and 21-24 are pending.

2. Applicant's election without traverse of Group III, claims 1-20 (now claims 1-5, 8, 10, 12-14, 16 and 21-24) drawn to a method for treating a LFA-l-mediated disorder in a mammal comprising administering an initial dosing of an anti-CDlla antibody filed on 10/25/04, is acknowledged.

3. Claims 1-5, 8, 10, 12-14, 16 and 21-24 are under examination as they read on a method for treating a LFA-l-mediated disorder in a mammal comprising administering an initial dosing of an anti-CDlla antibody.

4. The specification on page 1 should be amended to reflect the status of parent application No. 10/208,112.

5. Applicant's IDS, filed 11/15/04 is acknowledged.

6. The amendment filed 10/25/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The amendment filed on 10/25/04 to the paragraph beginning at page 16, lines 15 substituting "an intraclass chimera" with "a chimeric antibody" represents a departure from the specification and the claims as originally filed. Applicant submits that the amendment was made to correct typographical errors. However, the specification and the claims as originally filed have no support for the new replacement of a chimeric antibody. Applicant is creating a new genus of chimeric antibodies. A subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads, see *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972).

Applicant is required to cancel the new matter in the response to this Office action.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-5, 8, 10, 12-14, 16 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,690,933, (IDS Ref No. 11) or US. Pat. No. 5,854,070 (IDS No. 13) in view of U.S. Patent No. 5,403,919, (IDS Ref No.7).

The `070 patent teaches the antibodies that bind LFA-1 could be useful in treating inflammatory processes and in alleviating symptoms associated with inflammatory diseases, including arthritis and multiple sclerosis (see col., 1, lines 33-40 and col., 22, lines 42-67 in particular). The `070 patent further teaches that the antibodies include chimeric and/or CDR-grafted (including humanized) antibodies (see col., 4, lines 62-65 in particular). The `070 patent further teaches that in choosing human frameworks, two general criteria were used: (1) the human frameworks chosen were as homologous as possible to those of 23F2G in order to increase the probability that the CDR regions would retain their correct conformations and consequently their affinity towards the antigen and (2) the human framework regions chosen contained a minimal number of unusual residues that could potentially provoke an immune response against the antibody in a human (see col., 16, lines 54-64 in particular). Finally, the `070 patent teaches a CD11a mAb, a non-depleting mAb can be used (see col. 3, lines 31-34 in particular).

The `933 patent teaches the use of a CD11a mAb, a non-depleting mAb, in conjunction with other immunosuppressives including non-depleting and depleting antibodies, to treat autoimmune diseases such as multiple sclerosis (see col., 3, lines 11-55in particular). The `933 patent further teaches that the amount of therapeutic antibodies depending on the level to which it is desired to reduce the relevant population of T cells and condition which is being treated (see col., 4 lines 26-43 in particular). Finally, the `933 patent teaches that all mAb administrations are given parenterally, for example intravenously, subcutaneously (see col. 4, lines 55-65 in particular).

The claimed invention differs from the reference teachings only by the recitation of the antibody is administered to the mammal not more than once per week during the subsequent intermittent dosing in claim 1, wherein the subsequent dosing is less than about 50%, 25%, 10%, 2% calculated on a daily basis, of the initial dosing of the antibody in claims 2-5, wherein the initial dosing consists of daily administration in claim 13, wherein the intermittent dosing comprises administration of the antibody no more than once biweekly in claim 14, wherein the intermittent dosing is administered to the mammal for at least about 5 weeks in claim 23, or 10 weeks in claim 24.

The '919 patent teaches that doses for individuals and for different disease by measuring the effect of the antibody on the lessening of those parameters which are indicative of the disease being treated, including periodic repeated dosing (see col. 8, lines 13-50 in particular).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of treating rheumatoid arthritis or multiple sclerosis using anti-CD11a antibodies and further comprising administering an effective amount of an immunosuppressive agent taught by the '933 or '070 with dosing such as once per week or biweek as well as over extended periods of time such as at least about 5-10 weeks.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because such CD11a -specific antibodies induce tolerance and non T cell depleting as taught by '933 patent, and further because the use of modifying therapy to meet the needs of the patients including periodic treatment for chronic diseases such as autoimmune disease taught by '919 patent.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
January 7, 2005

Christina Chan

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600